Complete Summary

GUIDELINE TITLE

The role of calcium in peri- and postmenopausal women: 2006 position statement of The North American Menopause Society.

BIBLIOGRAPHIC SOURCE(S)

The North American Menopause Society. The role of calcium in peri- and postmenopausal women: 2006 position statement of the North American Menopause Society. Menopause 2006 Nov-Dec;13(6):862-77; quiz 878-9. [117 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: The role of calcium in peri- and postmenopausal women: consensus opinion of The North American Menopause Society. *Menopause* 2001 Mar-Apr;8(2):84-95.

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT

CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Osteoporosis and other diseases and disorders associated with calcium requirements in peri- and postmenopausal women, including colorectal cancer, hypertension, nephrolithiasis, and obesity

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness Counseling Evaluation Prevention

CLINICAL SPECIALTY

Endocrinology
Family Practice
Geriatrics
Internal Medicine
Nursing
Nutrition
Obstetrics and Gynecology
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses Allied Health Personnel Health Care Providers Health Plans Managed Care Organizations Nurses Pharmacists Physician Assistants Physicians

GUIDELINE OBJECTIVE(S)

- To update the evidence-based consensus opinion published by The North American Menopause Society (NAMS) in 2001 on the role calcium in peri- and postmenopausal women
- To provide guidance on the role of calcium in peri- and postmenopausal women to health professionals caring for this population

TARGET POPULATION

Peri- and postmenopausal women in North America

INTERVENTIONS AND PRACTICES CONSIDERED

- 1. Assessment for adequate calcium and vitamin D intake
- 2. 25(OH)D test for vitamin D deficiency
- 3. Encouraging adequate intake of calcium through diet or calcium supplements

MAJOR OUTCOMES CONSIDERED

Morbidity and mortality associated with calcium-deficient conditions in peri- and postmenopausal women

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources) Hand-searches of Published Literature (Secondary Sources) Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

For this revision, The North American Menopause Society (NAMS) conducted a search of the medical literature published since the consensus opinion was submitted for publication in November 2000. Using the database MEDLINE, a search was made for systematic reviews, meta-analyses, clinical trials, and clinical practice guidelines published in English and related to calcium and calcium therapy in peri- and postmenopausal women. The Medical Subject Headings used for the search were calcium with subheadings for physiology, deficiency, dose, therapeutic use, and adverse effects. Also searched were osteoporosis, colorectal cancer, hypertension, nephrolithiasis, obesity, vitamin D, and magnesium. The Cochrane Library was searched for relevant systematic reviews, and the National Guideline Clearinghouse was searched for relevant clinical practice guidelines. Priority was given to evidence from randomized, controlled clinical trials and meta-analyses of such trials, followed by evidence from controlled observational studies, using criteria described elsewhere. Recommendations from other evidence-based guidelines were also reviewed. Because standards of care and available treatment options differ throughout the world, the focus was limited to therapies available in North America.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

To help with this revision, The North American Menopause Society (NAMS) enlisted a five-person Editorial Board composed of endocrinologists, epidemiologists, and nutritionists from both clinical practice and research with expertise in calcium and/or women's health. The Editorial Board reviewed the previous consensus opinion and the more recently published data, compiled supporting statements and conclusions, and made recommendations. If the evidence was contradictory or inadequate to form a conclusion, a consensus-based opinion was established. (Practice parameter standards related to NAMS position statements have been described in an editorial in Boggs PP, Utian WH. The North American Menopause Society develops consensus opinions. *Menopause*.1998;5:67-68.)

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

This consensus opinion was reviewed by the Board of Trustees of The North American Menopause Society. It was edited, modified, and subsequently approved by The North American Menopause Society on August 9, 2006.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Summary

 Adequate calcium intake (in the presence of adequate vitamin D status) has been shown to reduce bone loss in peri- and postmenopausal women and reduce fractures in postmenopausal women older than age 60 with low calcium intakes. Calcium strongly enhances the bone-protective effects of estrogen/estrogen combined with a progestogen in postmenopausal women. Adequate calcium is considered a key component of any treatment regimen for patients with established osteoporosis.

- A woman's calcium requirement increases at menopause (or whenever estrogen is lost). This is because calcium absorption efficiency and renal conservation are both estrogen dependent, and both deteriorate in the estrogen-deprived state.
- The target calcium intake for most postmenopausal women is 1,200 mg/day.
- Adequate vitamin D status, defined as serum 25(OH)D of 30 ng/mL or more, is required to achieve the nutritional benefits of calcium. This level is usually achieved with a daily oral intake of at least 400 to 600 IU.
- Foods should be the primary source of calcium intake. Dairy products are among the best sources of calcium based on their calcium content, absorption, content of other essential nutrients, and low cost relative to total nutritional value. Approximately 3 cups of dairy products daily provide the 1,200-mg target.
- Supplements and fortified foods are an alternative source for women not able
 to consume enough dietary calcium to reach the recommended daily intake.
 Calcium supplements are best taken with meals and in divided doses
 (typically 500 mg or less at one time) to maximize absorption. Because
 calcium bioavailability varies from product to product, name-brand
 supplements that have been tested to demonstrate consistent bioavailability
 are recommended.
- There are no reported cases of calcium intoxication from food sources, and cases associated with supplements are rare.
- Calcium, like most nutrients, has beneficial effects in many systems. In addition to protection of bone mass and reduction of excessive bone remodeling, calcium is associated with small reductions in the risk of colorectal cancer, hypertension, renal calculi, and obesity.
- Based on the generally consistent animal and human data, a case can be made that calcium intake greater than or equal to the current recommended calcium intake provides some chemoprotective properties against colorectal cancer.
- Trials have demonstrated that a calcium intake of at least 1,200 mg/day is associated with a beneficial effect on systolic blood pressure. However, further research is needed.
- Calcium intake of up to 1,500 mg/day has been found to reduce the risk of developing renal calculi, but one study has found a 17% increased risk at 2,150 mg/day. For women at high risk of developing renal calculi, foods may be the best sources of calcium. If calcium supplementation is needed, each dose must not exceed the age-appropriate allowance and should be taken with a large glass of water, as avoiding dehydration is an important practice for these patients.
- Although limited data suggest a statistically strong inverse correlation between the risk of obesity and dietary calcium intake, available studies indicate that calcium intake explains only a small portion of the variability in body weight in postmenopausal women. Nevertheless, ensuring an adequate calcium intake for skeletal purposes may confer small weight-control benefits as well.
- Because no accurate test to determine calcium deficiency exists, clinicians should focus instead on encouraging a woman to consume enough calcium to meet the recommended levels through diet and, when necessary, calcium supplements. Laboratory tests for serum vitamin D should be for 25(OH)D, which are useful in identifying women who are vitamin D deficient and therefore likely to be calcium deficient even when ingesting adequate amounts of calcium from diet and supplements.

 Average calcium consumption is far below the amount recommended for optimal bone health, and many U.S. healthcare providers do not recommend calcium supplements as part of pharmacotherapy. Encouraging adequate intake of calcium should be a goal of all healthcare management of peri- and postmenopausal women.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

The position statement was based on the previous consensus opinion and review of more recently published data. When the evidence was contradictory or inadequate to form a conclusion, expert opinion-based decisions were made.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Adequate calcium intake (in the presence of adequate vitamin D status) has been shown to reduce bone loss in peri- and postmenopausal women and reduce fractures in postmenopausal women older than age 60 with low calcium intakes. Adequate calcium is considered a key component of any bone-protective therapeutic regimen.
- Calcium has also been associated with beneficial effects in several nonskeletal disorders, primarily hypertension, colorectal cancer, obesity, and nephrolithiasis, although the extent of those effects has not been fully elucidated.

POTENTIAL HARMS

- The side effect profile from recommended levels of calcium intake is insignificant. Calcium intervention trials have not reported any serious adverse events. Nevertheless, some women have difficulty swallowing the large tablet or have gastrointestinal (GI) adverse effects (i.e., gaseousness, constipation).
- Calcium intake greater than the Institute of Medicine (IOM) recommendations
 produces no currently recognized health benefits in women, and adverse
 events might be more likely to occur. Intake of more than 2,500 mg/day (the
 upper limit for healthy adults set by the IOM) can increase the risk of
 hypercalcemia, which, in extreme cases, can lead to kidney damage.
- The safe upper limit of vitamin D is 2,000 IU/day. Higher doses may cause vitamin D intoxication and increased risk of hypercalciuria and hypercalcemia.

CONTRAINDICATIONS

CONTRAINDICATIONS

A woman diagnosed with renal calculi should not consume calcium supplements above the level recommended for her age until the specific cause has been determined.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

Because standards of care and available treatment options differ throughout the world, the focus was limited to therapies available in North America.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Slide Presentation Staff Training/Competency Material

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

The North American Menopause Society. The role of calcium in peri- and postmenopausal women: 2006 position statement of the North American Menopause Society. Menopause 2006 Nov-Dec;13(6):862-77; quiz 878-9. [117 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2001 Mar (revised 2006 Dec)

GUIDELINE DEVELOPER(S)

The North American Menopause Society - Private Nonprofit Organization

SOURCE(S) OF FUNDING

The development of this position statement was supported by an unrestricted educational grant from GlaxoSmithKline Consumer Healthcare.

GUIDELINE COMMITTEE

Editorial Board

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The North American Menopause Society (NAMS) is committed to ensuring balance, independence, and objectivity in all its educational activities. All those involved in the development of a continuing medical education (CME) activity are required to disclose financial relationships they or their spouse/partner have had during the last 12 months with a commercial interest whose products or services are discussed in the CME activity content over which they have control or with any commercial supporters of the activity.

For the Editorial Board, Drs. Bilezikian, Heaney, Holick, Nieves, and Weaver report no significant financial relationships with any healthcare products or services that were discussed in this CME activity. For the NAMS Board of Trustees who are not serving on the Editorial Board, Dr. Freedman reports Alexza, Duramed, GlaxoSmithKline, Novartis, Organon, Pfizer, Vela, Wyeth (consultant), GlaxoSmithKline, National Institutes of Health, Organon (research support); Dr. Gallagher reports GlaxoSmithKline, Organon, Pfizer, Wyeth (consultant), Organon, Pfizer, Wyeth (research support); Dr. Goldstein reports Eli Lilly, Merck, Pfizer, Procter & Gamble, TAP (advisory boards); Dr. Gorodeski reports Molecular Diagnostics (advisory board); Dr. Henderson reports Council on Hormone Education (consultant); Dr. Pinkerton reports Duramed, Eli Lilly, Merck, Procter & Gamble, Roche, Solvay (consultant), Berlex, Eli Lilly, Pfizer/Alta, Procter & Gamble, Wyeth (speakers' bureau), Eli Lilly, Merck, Pfizer, Procter & Gamble, Solvay, Wyeth (research support), Council on Hormone Education (executive committee); Dr. Reame reports Procter & Gamble (consultant), Novo Nordisk, Procter & Gamble (research support); Dr. Richardson reports Procter & Gamble (consultant); Dr. Rothert reports no significant financial relationships; Dr. Schiff reports *Pause*—the consumer magazine of the American College of Obstetricians and Gynecologists (advisory board), Menopause—the official journal of The North American Menopause Society (Editor-in-Chief); Dr. Speroff reports Barr (consultant), Berlex, Organon, Wyeth (research support); Dr. Stuenkel reports no significant financial relationships; Dr. Utian reports Barr/Duramed, Berlex, Johnson & Johnson Pharmaceutical Research and Development, Merck, Merrion, Novartis, Organon, Pfizer, Roche/GlaxoSmithKline (consultant, advisory board), Amylin, 3M, Barr, Berlex, Bristol- Myers Squibb, Duramed, Eli Lilly, Forest, Glen, Glaxo- SmithKline, Johnson & Johnson, Neurocrine Biosciences, Novartis, Novo Nordisk, Organon, Pharmacia, Procter & Gamble, Pfizer, Roche, Sepracor, Solvay, Wyeth, Yamanouchi (research support). For additional contributors, Ms. Boggs, Dr. Graham, and Ms. Wisch all report no significant financial relationships.

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GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from <u>The North</u> American Menopause Society Web site.

Print copies: Available from NAMS, P.O. Box 94527, Cleveland, OH 44101, USA Order forms are available from The North American Menopause Society Web site, www.menopause.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

• Key Points: NAMS 2006 Position Statement on Calcium. Slide set. 2006. 17 p. Available from The North American Menopause Society (NAMS) Web site.

- NAMS continuing medical education activity. *Menopause* 2006 Nov-Dec;13(6): 878-80. Available from The North American Menopause Society Web site.
- Boggs PP, Utian WH. The North American Menopause Society develops consensus opinions. *Menopause* 1998 Summer;5(2):67-8. Available from the NAMS Web site.

Print copies: Available from NAMS, P.O. Box 94527, Cleveland, OH 44101, USA Order forms are available from The North American Menopause Society Web site, www.menopause.org.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on May 7, 2001. It was verified by the guideline developer as of June 7, 2001. This NGC summary was updated by ECRI on January 9, 2007. The updated information was verified by the guideline developer on February 6, 2007.

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